

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

Minneapolis Firefighter's Relief,
Association, et al.,

Civil No. 08-6324 PAM/AJB

Plaintiffs,

v.

**ORDER ON MOTION TO COMPEL
RESPONSES AND PRODUCTIONS**

Medtronic, Inc., et al.,

Defendants.

This action is before the court, Chief Magistrate Judge Arthur J. Boylan, on plaintiffs' motion to compel production of documents and responses to interrogatories. Hearing was held on December 21, 2011, at the U.S. Courthouse, 300 South Fourth St., Minneapolis, Minnesota 55415. Plaintiffs were represented by Eli Greenstein, Esq., Jennifer Joost, Esq., Michael Blatchly, Esq., James Hughes, Esq., and Karl Cambronne, Esq. Defendants were represented by Peter Carter, Esq., Emily Nicklin, Esq., and Patrick Williams, Esq.

Based upon the file and records in this matter, including memorandums, affidavits, exhibits, and arguments of counsel, the magistrate judge makes the following:

ORDER

1. Plaintiffs' Motion to Compel Production of Documents and Responses to Interrogatories is **granted in part and denied in part** as further provided herein [Docket No. 259].

2. Plaintiffs' motion to compel response to First Set Interrogatory No. 1, seeking financial information relating to off-label INFUSE uses, is **denied**. Medtronic opposes the discovery request on the ground that it does not maintain discreet sales and financial records

regarding off-label INFUSE use. Defendant asserts that it is the medical providers that determine how INFUSE is used in a particular surgical procedure. Medtronic does not control such use and does not maintain records tracking sales by intended or actual use, and therefore has no records distinguishing between on-label or off-label use. Defendant acknowledges that sales estimates relating to off-label use were generated and states that general estimates and projections have been produced to the plaintiffs by reference to PowerPoint presentations. Though the court finds that the interrogatory seeks information that is relevant and would be discoverable, plaintiffs have not persuasively established that the requested financial information exists in a record format currently maintained by Medtronic, and the court declines to compel the defendant to create or compile such records. The motion is therefore denied.

3. Plaintiffs' motion to compel responses to Interrogatory No. 2, seeking identities and compensation of "Key Opinion Leaders" (KOLs); Interrogatory No. 3, seeking compensation information relating to third-party consultants, medical organizations, and other entities involved in training, marketing, promotion, sales and other activities involving INFUSE; and Interrogatory No. 4, seeking summary information relating to doctor-consultants or third-party consulting and royalty arrangements, contracts, and other agreements regarding INFUSE, is **granted in part and denied in part** as stated herein.

Plaintiffs seek to obtain a listing of spine specialists with whom Medtronic conferred as consultants on matters relating to INFUSE. Plaintiffs point to express references to KOLs and KOL lists contained in Medtronic communications as clear internal recognition of their existence. The defendant contends that as a corporation it does not have an opinion as to who the KOLs might be with respect to discrete medical issues and it does not maintain a list of

specific consultants defined as KOLs. Medtronic confirms that the term is used in the industry as a shorthand reference to medical consultants and program participants, but insists that no definitive list exists, and to the extent the term is used by an individual employee, it is merely the employee's opinion and applies only to the particular narrow medical issue under consideration. In response to the interrogatory seeking KOL disclosures, Medtronic asserts that the discovery is duplicative of Interrogatory No. 3, relating to identification of consultant doctors having contracts in connection with INFUSE. Defendant represents that in response to Interrogatory No. 3 it has provided information regarding annual payments and the reasons for such payments made to over 150 consultant doctors and others. Medtronic objects to plaintiffs' demands that INFUSE payments to consultants be separated from other payments, and that individual payments rather than annualized payments to doctors be provided, on grounds that the discovery would be unduly burdensome. Medtronic also objected to Interrogatory No. 4 as being over broad and unreasonably burdensome, but states that a list of 220 contracts has been produced and certain contracts might be produced upon specific request. However, the defendant objects to any requirement that is provide a summary or description of services provided relating to INFUSE. It is the court's determination that Interrogatory Nos. 2, 3, and 4 are significantly duplicative and demand productions that are unreasonably burdensome. The court further accepts the defendant's position that no definitive KOL list exists, but also finds that the KOL concept is alive among Medtronic employees who rely upon consultants to some degree and the opinions of those employees is discoverable. However, the number of consultants with respect to which the plaintiffs request detailed information is excessive and compelling a full response would be unduly burdensome. Therefore, the court will fashion a discovery process as follows:

Medtronic shall survey those employees who regularly consult with doctors in regards to INFUSE and other spine products to determine the extent to which individual consultants may be regarded as Key Opinion Leaders. Each surveyed employee shall be given the names of the individual consultants identified by the defendant in its response to Interrogatory No. 3. A chart/questionnaire shall be constructed on which the employee will indicate, to his/her knowledge, the degree of each consultant's professional consulting relationship with Medtronic on a graded scale and whether the consultant is explicitly considered a KOL; the employee shall indicate the time span in which the employee is aware that a consulting relationship existed; and the employee shall concisely describe the specific area of consultation.¹ The results of this survey shall be produced to the plaintiffs who may then use the data to select a total of 20 individual consultants from the list for whom the defendants shall be required to produce the information requested in Interrogatory Nos. 2, 3, and 4 including a description of the engagement, the dates and amounts of compensation relating to INFUSE, the dates ranges of agreements or documents relating to the particular consultant, and a summary description of the services provided by the consultant.

4. Plaintiffs' motion to compel response to Interrogatory No. 5, seeking facts

¹ The parties shall confer to create an easy-to-use and effective survey chart. A menu of time spans and consultation specialties could be provided, and the nature and/or levels of contacts could be defined for grading purposes. The court is not advised of the basis of the relationships between particular Medtronic employees and particular consultants and the parties are therefore advised to incorporate those considerations into the survey, with emphasis on simplicity. Likewise, the parties can determine the criteria on which consultant grading should be considered.

supporting defendants' Eighth Affirmative Defense² is **denied**. The court agrees with defendant's position that the interrogatory is properly characterized as a contention interrogatory, i.e. an interrogatory seeking facts to support a pleading contention. Medtronic responded to the question by stating that its officers acted in good faith and without scienter, with some additional explanation. Plaintiffs now complain that the response does not contain facts to support claims of lack of scienter and other general assertions. Defendant argues that its response is sufficient and the demand for specific facts is premature.

Fed. R. Civ. P. 33(a)(2) states:

An interrogatory is not objectionable merely because it asks for an opinion or contention that relates to fact or the application of law to fact, but the court may order that the interrogatory need not be answered until designated discovery is complete, or until a pretrial conference or some other time.

Nonetheless, a contention interrogatory may be found to be over broad if it seeks all facts supporting a claim or defense such that a narrative account of the defendant's case would be required to fully respond. Shqeirat v. U.S. Airways Group, Inc., Civ. No. 07-1513 ADM/AJB, 2008 WL 4232018 at *4 (D. Minn. Sept. 9, 2008) (citing Moses v. Halstead, 236 F.R.D. 667, 674 (D. Kan. 2006)). In their motion to compel further response to Interrogatory No. 5 plaintiffs simply treat the interrogatory as any other fact-seeking discovery though the question essentially demands a narrative explanation for the denial of individual liability. Defendant has provided a general description of this affirmative defense and perhaps thereby provided some guidance for

² The Eighth Affirmative Defense states: "Lead plaintiffs' claims are barred, in whole or in part, because the Individual Defendants acted in good faith and did not culpably participate in, or directly or indirectly cause or induce, any act, statement and/or omission upon which Lead Plaintiffs base their claims." Defendants' Answer to Consolidated Class Action Complaint, page 54 [Docket No. 102].

more directed fact discovery. However, under the present circumstances the court finds the discovery to be over broad, as exemplified by the defendant's Interrogatory response that "[t]he facts supporting [the Eighth Affirmative] defense are too numerous to list."

5. Plaintiffs' motion for production of documents relating to consulting agreements with Key Opinion Leaders and other third parties involved in INFUSE activities pursuant to First Set Request Nos. 65 and 74 and Second Set Request No. 3 is **granted in part and denied in part** as stated herein. The motion is denied to the extent that plaintiff seeks "all documents relating to payment to physicians, surgeons or other medical professional and institutions relating to marketing, promotion, sale, safety and/or use of INFUSE." Plaintiffs' motion for agreements with consultants is granted with respect to the 20 individuals identified by the plaintiffs as persons for whom the defendants shall be required to produce the information requested in Interrogatory Nos. 2, 3, and 4 as provided above.

Defendant has objected to the plaintiffs' demands in First Set Nos. 65 and 74, and Second Set No. 3 as over broad and unduly burdensome, asserting that the discovery response would entail the physical examination of materials contained in hundreds of boxes stored in Memphis, Tennessee, which relate to Medtronic's entire Spine division. Defendant represents that the documents are not sorted by reference to INFUSE and that electronically stored documents responsive to the requests have been produced. Medtronic insists that the document search and compilation requested by the plaintiffs would be an enormous and prohibitively expensive burden which it should not be compelled to undertake, particularly in light of a compromise agreement between the parties regarding this discovery. Plaintiffs acknowledge an agreement with the defendant in an effort to narrow the requests by limiting the scope to

INFUSE documents, but contends that defendant merely produced incomplete and inadequate summaries which fail to satisfy the discovery compromise, particularly with respect to Second Set No. 3, relating to payments to third-parties.

The court finds that the document requests seeks relevant material, but further finds that the burden or expense of the proposed discovery outweighs its likely benefit, Fed. R. Civ. P. 26(b)(2)(C)(iii), and the full discovery proposed by the plaintiffs will not be required. Nonetheless, the court is not persuaded that the defendant's extrapolation of the costs of culling the Memphis records, based upon a previous production relating to six individuals, is a wholly accurate reflection of the ultimate cost of the proposed discovery. Disclosures responsive to First Set Nos. 65 and 74 shall therefore be required with respect to 20 consultants identified pursuant to processes outlined in paragraph 2 of this Order. The production shall be limited to documents pertaining to INFUSE. As to plaintiffs' request for additional documents reflecting payments to third party education, consulting, auditing or marketing firms for work relating to INFUSE, pursuant to Second Set Request No. 3, the motion to compel is denied. Plaintiffs have simply not established an evidentiary benefit that outweighs the expense or burden of production.

6. Plaintiffs' motion for production of documents relating to FDA warning letters and meetings concerning defendants' "serious corporate-wide issue" relating to off-label promotional activities pursuant to Second Set Request No. 39 is **denied**. Defendant contends that the discovery is not relevant because the warnings do not focus on INFUSE. Based upon inferences from other documents, plaintiff's argue that INFUSE was among the several products that Medtronic was promoting for off-label use which were the subject of FDA warning letters

citing a serious corporate-wide issue with Medtronic's promotion and advertising. Defendant disputes this inference and states that INFUSE materials relating to October 2007, FDA communications have been produced and plaintiffs are demanding FDA correspondence that exclusively concerns other products. The document request seeks INFUSE materials and the court finds no grounds on which to compel production of documents that do not relate to INFUSE. The motion to compel response to Second Set Request No. 39³ is denied.

Dated: January 19, 2012

s/Arthur J. Boylan
Arthur J. Boylan
United States Chief Magistrate Judge

³ Plaintiffs' memorandum argues in support of a response to Second Set Request No. 39. Defendant's memorandum contains a footnote advising the court that plaintiffs' brief inadvertently refers to this production request as number 39, and the request is actually No. 40. However, Second Set Request No. 39 as stated in Ex. 3 to the Affidavit of Eli Greenstein does seem to correspond to the plaintiffs' numbering reference, while Second Set Request No. 40 does not, though Second Set Request No. 40 as cited in Plaintiffs' Second Set of Requests provided as Ex. 2 to the Decl. of Patrick Williams is in fact the same request. In any event, the court has not found, and is not recommending, a direct request for documents relating to FDA concern about any unspecified "serious corporate-wide issue."